

Public Health Service, HHS

§ 88.1

§ 87.9 Which other HHS regulations apply?

Several other regulations apply to grants under this part. These include, but are not limited to:

- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 46—Protection of human subjects
- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearing under part 80 of this Title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

[49 FR 38117, Sept. 27, 1984]

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

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AUTHORITY: 42 U.S.C. 300mm–300mm–61, Pub. L. 111–347, 124 Stat. 3623.

SOURCE: 76 FR 38930, July 1, 2011, unless otherwise noted.

§ 88.1 Definitions.

Act means the Title XXXIII of the Public Health Service Act, as amended, 42 U.S.C. 300mm through 300mm–61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub.L. 111–347), which created the World Trade Center (WTC) Health Program.

Aggravating means a health condition that existed on September 11, 2001, and that, as a result of exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, requires medical treatment that is (or will be) in addition to, more frequent than, or of longer duration than the medical treatment that would have been required for such condition in the absence of such exposure.

Certification means review and approval by the WTC Program Administrator of a screening-eligible survivor as eligible for monitoring and treatment, or a WTC-related health condition or a health condition medically associated with a WTC-related health condition in a particular WTC responder or certified-eligible survivor for the purpose of reimbursement of expenses for medically necessary treatment.

Certified-eligible survivor means:

(1) An individual who has been identified as eligible for medical treatment and monitoring as of January 2, 2011; or

(2) A screening-eligible WTC survivor who the WTC Program Administrator certifies to be eligible for follow-up monitoring and treatment under § 88.10(f).

Clinical Center of Excellence means a center or centers under contract with the WTC Health Program. A Clinical Center of Excellence:

(1) Uses an integrated, centralized health care provider approach to create a comprehensive suite of health services that are accessible to enrolled

WTC responders, screening-eligible WTC survivors, or certified-eligible survivors;

(2) Has experience in caring for WTC responders or screening-eligible and certified-eligible WTC survivors;

(3) Employs health care provider staff with expertise that includes, at a minimum, occupational medicine, environmental medicine, trauma-related psychiatry and psychology, and social services counseling; and

(4) Meets such other requirements as specified by the WTC Program Administrator.

Data Center means a center or centers under contract with the WTC Health Program to:

(1) Receive, analyze, and report to the WTC Program Administrator on data that have been collected and reported to the Data Center by the corresponding Clinical Center(s) of Excellence;

(2) Develop monitoring, initial health evaluation, and treatment protocols with respect to WTC-related health conditions;

(3) Coordinate the outreach activities of the corresponding Clinical Centers of Excellence;

(4) Establish criteria for credentialing of medical providers participating in the nationwide provider network;

(5) Coordinate and administer the activities of the WTC Health Program Steering Committees; and

(6) Meet periodically with the corresponding Clinical Center(s) of Excellence to obtain input on the analysis and reporting of data and on development of monitoring, initial health evaluation, and treatment protocols.

Designated representative means an individual selected by a WTC responder, a screening-eligible or a certified-eligible survivor to represent his or her interests to the WTC Health Program.

Ground Zero means a site in Lower Manhattan bounded by Vesey Street to the north, the West Side Highway to the west, Liberty Street to the south, and Church Street to the east in which stood the former World Trade Center complex.

Health condition medically associated with a World Trade Center (WTC)-related health condition means a condition that

results from treatment of a WTC-related health condition or results from progression of a WTC-related health condition.

Initial health evaluation means assessment of one or more symptoms that may be associated with a WTC-related health condition and includes a medical and exposure history, a physical examination, and additional medical testing as needed to evaluate whether the individual has a WTC-related health condition and is eligible for treatment under the WTC Health Program.

Interested party means a representative of any organization representing WTC responders, a nationally recognized medical association, a WTC Health Program Clinical Center of Excellence or Data Center, a State or political subdivision, or any other interested person.

List of WTC-related health conditions means the following disorders and conditions, including any other condition added to the list through procedures specified by the Act and under this part:

- (1) Aerodigestive disorders:
 - (i) Interstitial lung disease.
 - (ii) Chronic respiratory disorder [fumes/vapors].
 - (iii) Asthma.
 - (iv) Reactive airways dysfunction syndrome [RADS].
 - (v) WTC-exacerbated chronic obstructive pulmonary disease [COPD].
 - (vi) Chronic cough syndrome.
 - (vii) Upper airway hyperactivity.
 - (viii) Chronic rhinosinusitis.
 - (ix) Chronic nasopharyngitis.
 - (x) Chronic laryngitis.
 - (xi) Gastroesophageal reflux disorder [GERD].
 - (xii) Sleep apnea exacerbated by or related to a condition described in preceding paragraphs (1)(i) through (1)(xi) of this definition.
- (2) Mental health conditions:
 - (i) Posttraumatic stress disorder.
 - (ii) Major depressive disorder.
 - (iii) Panic disorder.
 - (iv) Generalized anxiety disorder.
 - (v) Anxiety disorder [not otherwise specified].
 - (vi) Depression [not otherwise specified].
 - (vii) Acute stress disorder.

- (viii) Dysthymic disorder.
- (ix) Adjustment disorder.
- (x) Substance abuse.
- (3) Musculoskeletal disorders for those WTC responders who received any treatment for a World Trade Center (WTC)-related musculoskeletal disorder (as defined in this section) on or before September 11, 2003:
 - (i) Low back pain.
 - (ii) Carpal tunnel syndrome [CTS].
 - (iii) Other musculoskeletal disorders.
 - (4) Cancers:
 - (i) Malignant neoplasms of the lip, tongue, salivary gland, floor of mouth, gum and other mouth, tonsil, oropharynx, hypopharynx, and other oral cavity and pharynx.
 - (ii) Malignant neoplasm of the nasopharynx.
 - (iii) Malignant neoplasms of the nose, nasal cavity, middle ear, and accessory sinuses.
 - (iv) Malignant neoplasm of the larynx.
 - (v) Malignant neoplasm of the esophagus.
 - (vi) Malignant neoplasm of the stomach.
 - (vii) Malignant neoplasm of the colon and rectum.
 - (viii) Malignant neoplasm of the liver and intrahepatic bile duct.
 - (ix) Malignant neoplasms of the retroperitoneum and peritoneum, omentum, and mesentery.
 - (x) Malignant neoplasms of the trachea; bronchus and lung; heart, mediastinum and pleura; and other ill-defined sites in the respiratory system and intrathoracic organs.
 - (xi) Mesothelioma.
 - (xii) Malignant neoplasms of the peripheral nerves and autonomic nervous system, and other connective and soft tissue.
 - (xiii) Malignant neoplasms of the skin (melanoma and non-melanoma), including scrotal cancer.
 - (xiv) Malignant neoplasm of the female breast.
 - (xv) Malignant neoplasm of the ovary.
 - (xvi) Malignant neoplasm of the prostate.
 - (xvii) Malignant neoplasm of the urinary bladder.
 - (xviii) Malignant neoplasm of the kidney.

(xix) Malignant neoplasms of the renal pelvis, ureter and other urinary organs.

(xx) Malignant neoplasms of the eye and orbit.

(xxi) Malignant neoplasm of the thyroid.

(xxii) Malignant neoplasms of the blood and lymphoid tissues (including, but not limited to, lymphoma, leukemia, and myeloma).

(xxiii) Childhood cancers: Any type of cancer diagnosed in a person less than 20 years of age.

(xxiv) Rare cancers: any type of cancer¹ that occurs in less than 15 cases per 100,000 persons per year in the United States.

Medical emergency means a physical or mental health condition for which immediate treatment is necessary.

Medically necessary treatment means the provision of services by physicians and other health care providers, diagnostic and laboratory tests, prescription drugs, inpatient and outpatient hospital services, and other care that is appropriate to manage, ameliorate or cure a WTC-related health condition or a health condition medically associated with a WTC-related health condition, and which conforms to medical treatment protocols developed by the Data Centers and approved by the WTC Program Administrator.

Monitoring means periodic physical and mental health assessment of a WTC responder or certified-eligible survivor in relation to exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks and which includes a medical and exposure history, a physical examination and additional medical testing as needed for surveillance or to evaluate symptom(s) to determine whether the individual has a WTC-related health condition.

¹Based on 2005–2009 average annual data age-adjusted to the 2000 U.S. population. See, Copeland G, Lake A, Firth R, Wohler B, Wu XC, Stroup A, Russell C, Boyuk K, Schymura M, Hofferkamp J, Kohler B (eds) [2012]. Cancer in North America: 2005–2009. Volume One: Combined Cancer Incidence for the United States, Canada and North America. Springfield, IL: North American Association of Central Cancer Registries, Inc.

Nationwide provider network means a network of providers throughout the United States under contracts with the WTC Health Program to provide an initial health evaluation, monitoring and treatment to enrolled responders and screening-eligible or certified-eligible survivors who live outside the New York metropolitan area.

New York City disaster area means an area within New York City that is the area of Manhattan that is south of Houston Street and any block in Brooklyn that is wholly or partially contained within a 1.5-mile radius of the former World Trade Center complex.

New York metropolitan area means the combined statistical areas comprising the Bridgeport-Stamford-Norwalk, CT Metropolitan Statistical Area; Kingston, NY Metropolitan Statistical Area; New Haven-Milford, CT Metropolitan Statistical Area; New York-Northern New Jersey-Long Island, NY-NJ-PA Metropolitan Statistical Area; Poughkeepsie-Newburgh-Middletown, NY Metropolitan Statistical Area; Torrington, CT Micropolitan Statistical Area; Trenton-Ewing, NJ Metropolitan Statistical Area, as defined in OMB Bulletin 10-02, December 1, 2009.

NIOSH means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

One (1) day means the length of a standard work shift, or at least 4 hours but less than 24 hours.

Pentagon site means any area of the land (consisting of approximately 280 acres) and improvements thereon, located in Arlington, Virginia, on which the Pentagon Office Building, Federal Building Number 2, the Pentagon heating and sewage treatment plants, and other related facilities are located, including various areas designated for the parking of vehicles, vehicle access, and other areas immediately adjacent to the land or improvements previously described that were affected by the terrorist-related aircraft crash on September 11, 2001; and those areas at Fort Belvoir in Fairfax County, Virginia and at the Dover Port Mortuary at Dover Air Force Base in Delaware involved in the recovery, identification, and trans-

portation of human remains for the incident.

Police department means any law enforcement department or agency, whether under Federal, state, or local jurisdiction, responsible for general police duties, such as maintenance of public order, safety, or health, enforcement of laws, or otherwise charged with prevention, detection, investigation, or prosecution of crimes.

Scientific/Technical Advisory Committee means the WTC Health Program Scientific/Technical Advisory Committee whose members are appointed by the WTC Program Administrator to review scientific and medical evidence and to make recommendations to the WTC Program Administrator on additional WTC Health Program eligibility criteria and on additional WTC-related health conditions.

Screening-eligible survivor means an individual who is not a WTC responder and who claims symptoms of a WTC-related health condition and meets the eligibility criteria for a survivor specified in § 88.8 of this part.

September 11, 2001, terrorist attacks means the terrorist attacks that occurred on September 11, 2001, in New York City, at Shanksville, Pennsylvania, and at the Pentagon, and includes the aftermath of such attacks.

Shanksville, Pennsylvania site means the property in Stonycreek Township, Somerset County, Pennsylvania, which is bounded by Route 30 (Lincoln Highway), State Route 1019 (Buckstown Road), and State Route 1007 (Lambertsville Road); and those areas at the Pennsylvania National Guard Armory in Friedens, Pennsylvania involved in the recovery, identification, and transportation of human remains for the incident.

Staten Island Landfill means the landfill in Staten Island, NY called “Fresh Kills.”

Terrorist watch list means the lists maintained by the Federal government that will be utilized to screen for known terrorists.

World Trade Center (WTC) Health Program means the program established by Title XXXIII of the Public Health Service Act as amended, 42 U.S.C. 300mm–300mm–61 (codifying Title I of the

James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347)), to provide medical monitoring and treatment benefits for eligible responders to the September 11, 2001, terrorist attacks and initial health evaluation, monitoring, and treatment benefits for residents and other building occupants and area workers in New York City who were directly impacted and adversely affected by such attacks.

World Trade Center (WTC) Program Administrator means the Director of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, or his or her designee.

World Trade Center (WTC)-related health condition means an illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with expertise in treating or diagnosing the health conditions in the list of conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition or a mental health condition. A WTC-related health condition includes conditions on the list of WTC-related health conditions as specified in this definition for WTC responders and certified-eligible survivors, and any other condition added to the list of WTC-related health conditions through procedures specified by the Act and under this part.

World Trade Center (WTC)-related musculoskeletal disorder means a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks.

World Trade Center (WTC) responder means an individual who has been identified as eligible for monitoring and

treatment as described in § 88.3 or who meets the eligibility criteria in § 88.4.

[76 FR 38930, July 1, 2011, as amended at 77 FR 24631, Apr. 25, 2012; 77 FR 56158, Sept. 12, 2012; 77 FR 62167, Oct. 12, 2012; 78 FR 18865, Mar. 28, 2013; 78 FR 57514, Sept. 19, 2013; 79 FR 9117, Feb. 18, 2014]

§ 88.2 General provisions.

(a) Designated representative. (1) An applicant, enrolled responder, screening-eligible survivor, or certified-eligible survivor may appoint one individual to represent his or her interests under the WTC Health Program. The appointment must be in writing.

(2) There may be only one representative at any time. After one representative has been properly appointed, the WTC Health Program will not recognize another individual as a representative until the appointment of the first designated representative is withdrawn.

(3) A properly appointed representative who is recognized by the WTC Health Program may make a request or give direction to the WTC Health Program regarding the eligibility or certification determinations under the WTC Health Program, including appeals. Any notice requirement contained in this part or in the Act is fully satisfied if sent to the designated representative.

(4) An enrolled responder, screening-eligible survivor, or certified-eligible survivor may authorize any individual to represent him or her in regard to the WTC Health Program, unless that individual's service as a representative would violate any applicable provision of law (such as 18 U.S.C. 205 and 208).

(5) A Federal employee may act as a representative only on behalf of the individuals specified in, and in the manner permitted by, 18 U.S.C. 203 and 18 U.S.C. 205.

(6) If a screening-eligible or certified-eligible survivor is a minor, a parent or guardian may act on his or her behalf.

(b) [Reserved]

§ 88.3 Eligibility—currently identified responders.

(a) Responders who were identified as eligible for monitoring and treatment under the arrangements as in effect on January 2, 2011, between NIOSH and